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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/537,766 | 06/06/2005 | Yasuki Itoh | 081356-0242 | 5454 |

22428 7590 09/19/2008

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| EXAMINER | |
|---|---|
| WALLENHORST, MAUREEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1797 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/19/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,766 | ITOH ET AL. | |
| | Examiner | Art Unit | |
| | Maureen M. Wallenhorst | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-8,10-21,23,24,37 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10-21,23,24,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2008 has been entered.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4-8, 12-21 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to independent claims 1 and 15 concerning the monovalent cation at a final concentration of less than 50 mmol/L represents new matter not described in the specification as originally filed since the specification states that the concentration of the monovalent cation "is 0-50 mmol/L", which includes the value of 50 mmol/L. See page 5, lines 9-10 and page 11, lines 7-8 of the specification as originally filed. While the range 0-50 mmol/L includes values less than 50 mmol/L, the range does not specifically exclude the value of 50 mmol/L as the phrase "less than 50 mmol/L" does. The

specification does not explicitly limit the concentration of the monovalent cation to less than 50 mmol/L, but rather includes the value of 50 mmol/L.

In addition, the amendment made to independent claim 15 concerning the "separation agent comprising a monovalent cation at a final concentration of less than 50 mmol/L" represents new matter not supported by the original specification since all embodiments taught in the specification include a polyanion and a divalent cation in addition to the monovalent cation. All embodiments in the specification specify that in order to precipitate LDLs other than small particle LDL, each of a polyanion and a divalent cation is required. The monovalent cation is taught as an optional component in addition to the required polyanion and divalent cation. See lines 6-16 on page 10 of the specification. Therefore, the specification as originally filed does not support an embodiment where LDLs other than small particle LDL are precipitated by a separation agent containing only a monovalent cation.

5. Claims 10-11 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In step (ii) of the method recited in claim 10, the phrase "eliminating HDL by treating the test sample from step (ii)" is indefinite since this phrase should refer to the sample from step (i) in order to make proper sense. The full meaning for the abbreviation "PEG" should be included in claim 10.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiuchi (WO 00/17388, English language equivalent is US 6,794,157).

Sugiuchi teaches of a method to separate lipoproteins other than HDL from a sample by combining the sample with an aggregating agent and/or a divalent metal salt. The aggregating agent can be polyethylene glycol (PEG), and since Sugiuchi teaches that an aggregating agent **and/or** a divalent metal salt may be used to precipitate lipoproteins other than HDL, the teaching encompasses the use of only PEG in order to precipitate or aggregate lipoproteins other than

HDL. The lipoproteins precipitated include low density lipoproteins. See lines 24-42 in column 6 of Sugiuchi.

Sugiuchi fails to teach that small particle LDL is also not precipitated in the method in addition to high density lipoproteins. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to realize that the PEG taught by Sugiuchi would precipitate LDLs and leave both HDL and small particle LDL in solution since small particle LDL is defined as having a higher density than standard LDL, and this higher density would simulate the higher density of HDL that allows for the HDL to remain in solution. Thus, one of skill in the art would also expect the higher density small particle LDL to remain in solution similar to the HDL when a test sample is combined with the aggregating agent PEG since the density property of the small particle LDL is more similar to the density property of HDL than to standard LDLs that precipitate upon combination with PEG. With regards to claim 24, it would have been obvious to one of ordinary skill in the art to vary the concentration of the PEG added to the test sample in the method taught by Sugiuchi since in the absence of any unexpected results, concentration is a result effective parameter that can be experimentally varied in order to achieve optimum results for a particular procedure.

10. Claim 10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method for quantifying small particle LDL, defined in the specification as lipoprotein smaller in particle size but higher in density than standard LDL, comprising the steps of removing lipoproteins other than small particle LDL and HDL from a test sample by adding a separation agent consisting of PEG, eliminating HDL by treating the test

sample with cholesterol esterase and cholesterol oxidase in the presence of polyalkylene oxide, and quantifying the small particle LDL leftover in the sample by measuring the amount of LDL.

11. Claims 11 and 38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

12. Applicant's arguments with respect to claims 1, 4-8, 10-21, 23-24 and 37-38 have been considered but are moot in view of the new ground(s) of rejection.

The previous objections to the claims, and each of the previous grounds of rejection of the claims under 35 USC 112, second paragraph, 35 USC 102 and 35 USC 103 made in the last Office action mailed on December 26, 2007 have been withdrawn in view of the amendments made to the claims. New grounds of rejection for the amended claims are set forth above. It is cautioned that if the claims are further amended to address the rejection set forth under 35 USC 112, first paragraph above for the inclusion of new matter, the references to Sugiuchi and JP 07294532 may apply again under 35 USC 102 or 35 USC 103.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1266. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

September 16, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797